UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

SOLVAY PHARMACEUTICALS, INC., Civil No. 03-2836 (JRT/FLN)

Plaintiff,

v.

ETHEX CORPORATION, and KV PHARMACEUTICAL COMPANY,

Defendants.

ORDER ON REPORT AND RECOMMENDATION OF MAGISTRATE JUDGE

John B. Gordon and Peter J. Goss, **FAEGRE & BENSON LLP**, 90 South Seventh Street, Suite 2200, Minneapolis, MN 55402; Lisa Horvath Shub and Saul H. Perloff, **FULBRIGHT & JAWORSKI LLP**, 300 Convent Street, Suite 2200, San Antonio, TX 78205; Marc B. Collier, **FULBRIGHT & JAWORSKI – AUSTIN**, 600 Congress Avenue, Suite 2400, Austin, TX 78701, for plaintiff.

William Z. Pentelovitch and Dawn C. Van Tassel, **MASLON EDELMAN BORMAN & BRAND**, LLP, 3300 Wells Fargo Center, 90 South Seventh Street, Minneapolis, MN 55402; and Thomas C. Morrison and Robert W. Lehrburger, **PATTERSON BELKNAP WEBB & TYLER LLP**, 1133 Avenue of the Americas, New York, NY 10036, for defendants.

Defendants seek partial summary judgment on plaintiff's Lanham Act claims. In a Report and Recommendation dated February 23, 2006, United States Magistrate Judge Franklin L. Noel recommended granting in part and denying in part defendants' motion. The parties have filed objections to the Magistrate Judge's Report and Recommendation. The Court has conducted a *de novo* review of the parties' objections pursuant to 28

U.S.C. § 636(b)(1)(C) and D. Minn. LR 72.2(b). For the reasons set forth below, the Court overrules in part and sustains in part the parties' objections and adopts in part and rejects in part the report and recommendation of the Magistrate Judge.

BACKGROUND

Defendants manufacture and market Pangestyme, a pancreatic enzyme. Pancreatic enzymes are used by patients who have a shortage of natural digestive enzymes, such as people suffering from pancreatitis or cystic fibrosis. Plaintiff produces Creon, a competing pancreatic enzyme. Defendants describe Pangestyme as a "branded generic" that they promote as a lower priced alternative to Creon.

Prescription pancreatic enzyme supplements are subject to FDA regulation. *See* Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301-92 (1982). The FDCA requires FDA approval, through a "new drug application" ("NDA") before a new drug may be put on the market. *Id.* at §§ 331(d), 355(a). A product similar to an NDA-approved drug may be approved and marketed based on an "abbreviated new drug application" ("ANDA"). *Id.* at § 355(j). An ANDA requires the manufacturer of the similar drug to demonstrate that the two drugs are therapeutically equivalent – that is, pharmaceutically equivalent and bioequivalent. *Id.* at § 355(j)(2)(A)(i)-(viii). In 1995, the FDA declared that all pancreatic enzyme drugs would require NDA or ANDA approval beginning in April 2008, but permitted such drugs to remain on the market during the approval process. *See* 69 Fed. Reg. 23410 (Apr. 28, 2004). Neither Creon nor Pangestyme has been tested, approved, or compared by the FDA.

Plaintiff brought the instant lawsuit in April 2003, alleging that defendants' advertising of Pangestyme is false and misleading under the Lanham Act and Minnesota state law. Plaintiff also requested a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202 that Pangestyme may not be lawfully substituted for Creon.

Defendants moved to dismiss all of plaintiff's claims, and in an Order dated March 30, 2004, the Court granted in part and denied in part defendants' motion. *Solvay Pharms., Inc. v. Ethex Corp.*, 2004 WL 742033 (D. Minn. Mar. 30, 2004). The Court denied defendants' motion as to plaintiff's Lanham Act and state law claims. The Court determined that plaintiff could attempt to establish a Lanham Act violation by providing evidence establishing the proper market definition of disputed terms, and stated that, based on the allegations in the complaint, plaintiff could "prove that Pangestyme and Creon are not substitutable, alternatives, equivalent, or comparable, and that any advertisement to the contrary is literally false." *Id.* at *4.

The Court granted defendants' motion to dismiss plaintiff's request for a declaratory judgment. *Id.* The Court found that the requested relief would affect individual pharmacists and pharmacist boards who were not parties to the case, and further, that the requested injunction would conflict with the laws of states permitting substitution based on independent judgments of therapeutic or pharmaceutical equivalence. In addition, the Court noted that plaintiff would still be able to pursue relief through its Lanham Act and state law claims despite the dismissal of their request for declaratory relief.

ANALYSIS

I. Defendants' Objection

Defendants object to the Magistrate Judge's recommendation to deny their motion for summary judgment on plaintiff's Lanham Act "substitutability" claim. Plaintiff alleges that defendants have falsely advertised that Pangestyme is "substitutable" for Creon. Defendants contend that this Lanham Act claim should be dismissed because it is simply a "restatement" of the declaratory judgment claim, which the Court dismissed in the March 30, 2004 Order. The Court disagrees.

The March 30, 2004 Order dismissing plaintiff's request for declaratory judgment does not foreclose plaintiff's ability to pursue claims under the Lanham Act. As set forth in the March 30, 2004 Order, the Court dismissed the declaratory judgment claim because the requested relief would have impermissibly impacted persons, including pharmacists and pharmacist boards, who are not party to the lawsuit. *Solvay*, 2004 WL 742033, at *4; *see also Solvay Pharms. v. Global Pharms.*, 298 F. Supp. 2d 880, 884-85, 887 (D. Minn. 2004) (dismissing declaratory judgment claim, denying motion to dismiss Lanham Act claim); *Healthpoint, Ltd. v. River's Edge Pharms.*, 2005 WL 356839, *6 (W.D. Tex. Feb. 14, 2005) (same). In contrast, plaintiff's Lanham Act claims would not impermissibly impact persons not party to the lawsuit, and the Court explicitly held that, based on the allegations in the complaint, plaintiff could pursue claims under the Lanham Act. The Court will therefore overrule defendants' objection.

II. Plaintiff's Objections

Plaintiff objects to the Magistrate Judge's recommendation to grant defendants' motion for summary judgment on its Lanham Act "safer and more effective" claim, as well as its Lanham Act "alternative" and "compare" claim.

Plaintiff alleges that defendants have falsely advertised that Pangestyme is "safer and more effective" than Creon. The Magistrate Judge recommended dismissing plaintiff's "safer and more effective" claim because it is undisputed that defendants have not used those terms in their advertisements. In its objection, plaintiff acknowledges that defendants' advertisements have not used those terms, however, plaintiff argues that defendants' advertisements nevertheless imply that Pangestyme is "safer and more effective" than Creon. In support of this contention, plaintiff points to one of defendants' advertisements, which depicts a smiling little girl holding her mother's hand as she leaves the doctor's office, with the statement "The Next Visit Could Be Even Better!" The advertisement also states that Pangestyme contains no organic solvents or acetone. Plaintiff argues that this advertisement "clearly asserts" that Pangestyme is safer than Creon. The Court disagrees.

First, as noted above, it is undisputed that the words "safer and more effective" do not appear in defendants' advertisements. Second, the statement that the next visit could be "better" would, at most, constitute non-actionable puffery. *See, e.g., Am. Italian Pasta Co. v. New World Pasta Co.*, 317 F.3d 387, 391 (8th Cir. 2004). Third, the statements regarding solvents and acetone, although specific, are not alleged to be false. Taken together, the Court finds that defendants' advertisements do not state that Pangestyme is

"safer and more effective" than Creon, either directly or by implication. Therefore, the Court grants defendants' motion for summary judgment on plaintiff's Lanham Act "safer and more effective" claim.

Plaintiff also alleges that defendants have falsely advertised that Pangestyme is an "alternative" to Creon, and invites consumers to "compare" Pangestyme to Creon. The Magistrate Judge recommended granting defendants' motion for summary judgment on this claim.

As an initial matter, the Court notes that the parties have apparently chosen to frame this issue very narrowly. Defendants argue that, as a matter of law, they are entitled to advertise Pangestyme as an "alternative" to Creon. However, the parties agree that for the purposes of the instant motion, the Court need not consider whether Pangestyme is a "bio-equivalent alternative" or a "therapeutically-equivalent alternative" to Creon. *See* Report and Recommendation, 12 n.2. Rather, the parties appear to request the Court to address the meaning of "alternative" and "compare" in a vacuum, divorced from considerations of bio-equivalence or therapeutic-equivalence.

At this stage in the proceedings, the Court is unpersuaded that "alternative" and "compare" may be considered separately from considerations of bio-equivalence or therapeutic-equivalence. In a motion for summary judgment, the moving party bears the initial burden of showing that there are no genuine issues of material fact and that the movant is entitled to judgment as a matter of law. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The Court finds that defendants have failed to meet that burden, and

therefore denies defendants' motion for summary judgment on plaintiff's "alternative" and "compare" Lanham Act claim.

ORDER

Based on the foregoing, all the records, files, and proceedings herein, the Court **OVERRULES** defendants' objection [Docket No. 167] and **SUSTAINS in part** and **OVERRULES in part** plaintiff's objection [Docket No. 171] and **ADOPTS in part** and **REJECTS in part** the Magistrate Judge's Report and Recommendation [Docket No. 153]. Accordingly, **IT IS HEREBY ORDERED** that defendants' Motion for Partial Summary Judgment [Docket No. 72] is **GRANTED in part** and **DENIED in part**, as follows:

1. Defendants' motion for summary judgment on plaintiff's allegations that defendants violate the Lanham Act by advertising that Pangestyme is "high quality," "safer or more effective than Creon," "safer or more effective than" competing enzymes because of its enteric coating, "safer or more effective than" competing enzymes because it is made in the United States, and that Pangestyme is endorsed or approved by the CFF, is **GRANTED**;

2. Defendants' motion for summary judgment on plaintiff's allegation that defendants violated the Lanham Act by advertising that Pangestyme "meets USP standards" is **DENIED**;

3. Defendants' motion for summary judgment on plaintiff's allegation that defendants violate the Lanham Act by falsely promoting Pangestyme as "substitutable" for Creon is **DENIED**;

4. Defendants' motion for summary judgment on plaintiff's allegation that defendants violate the Lanham Act by advertising Pangestyme as an "alternative" to Creon, or by inviting customers to "compare" Pangestyme to Creon is **DENIED**.

DATED: March 22, 2006
at Minneapolis, Minnesota.

s/ John R. Tunheim
JOHN R. TUNHEIM
United States District Judge